

Justification for Other than Full and Open Competition

"Source Selection Information – see FAR 2.101 and 3.104"

1. Identification of the agency and contracting activity. :

a. Federal agency and contracting activity. HHS.

Centers for Disease Control and Prevention

b. Sponsoring organization.

Coordinating Center for Infectious Diseases (CCID)
National Center for Zoonotic, Vector-borne and Enteric Diseases
(NCZVED)
Division of Viral and Rickettsial Diseases (DVRD)
Chronic Viral Diseases Branch (CVDB)

c. Project Officer information.

Project Officer name.

Joann House

Mailing address.

Centers for Disease Control and Prevention
Attn: Joann House
1600 Clifton Road, NE, Bldg 6, Rm 113, Mail Stop A-15
Atlanta, GA 30333

E-mail address. jsh4@cdc.gov

Telephone number. 404-639-3748

2. Nature and/or description of the action being approved.

a. Acquisition purpose and objectives. Sole source purchase of one (1) Chemagic Magnetic Separation Module I (Chemagic MSM 1) to include one year extended warranty. The instrument will be used to support high-throughput HPV DNA testing in support of HPV vaccine monitoring studies.

b. Project background.

Currently one HPV vaccine targeting four types (HPV 6, 11, 16, 18) is approved, and approval of another formulation is anticipated. Effective vaccine implementation requires CDC to conduct post-vaccine surveillance. This will require the HPV laboratory within CVDB to use high-throughput testing methods to detect and type HPV from a wide variety of biologic specimens obtained in surveillance studies. Current typing methods rely on PCR assays that require highly purified extracted

DNA for optimal sensitivity and specificity. The CVDB HPV laboratory needs an automated extraction platform that provides a walk-away high throughput method to extract DNA from cervical and other types of cells, formalin-fixed paraffin embedded tissue, and urine into a format that is adaptable to downstream laboratory testing procedures.

3. Description of the supplies or services required to meet the agency's needs (including the estimated value).

a. Project title.

Increase laboratory testing capacity in support of vaccine surveillance

b. Project description.

CVDB's HPV laboratory supports HPV vaccine surveillance studies. HPV testing based on HPV DNA detection and typing is required in nearly all surveillance studies to monitor changes in the type distribution in response to vaccination. This requires the laboratory to be able to increase the sample throughput without compromising the quality of testing. DNA extraction is currently one of the most time-consuming steps of the assay. This must be done accurately to avoid sample-to-sample contamination and in order to yield quality DNA for optimized results. A fully automated walk-away platform for DNA extraction of a variety of sample types is required to achieve high-throughput HPV DNA testing. In addition to the above requirements, other key features to meet programmatic needs are low cost of reagents, ability for user to adjust conditions and reliability.

Requirement type.

- ☐ Research & development (R&D)
- ☐ R & D support services
- ☐ Support services (non-R&D)
- ☒ Supplies/equipment
- ☐ Information technology (IT)
- ☐ Construction
- ☐ Architect-engineer (A & E) services
- ☐ Design-build
- ☐ Other (specify): _____

Type of action.

- ☒ New requirement
- ☐ Follow-on
- ☐ Other (specify): _____

Proposed contract/order type.

- ☒ Firm-fixed-price

- ☐ Other fixed-price (specify, e.g., fixed-price award-fee, fixed-price incentive-fee): _____
- ☐ Cost-plus-fixed-fee
- ☐ Other cost reimbursement (specify, e.g., cost-plus-award-fee, cost-plus-incentive-fee): _____
- ☐ Time and materials
- ☐ Indefinite delivery (specify whether indefinite quantity, definite quantity, or requirements): _____
- Other (specify): _____
- Completion Form ☐ Term form

Acquisition identification number.

Procurement Request # 00HCVHDG-2009-68977

c. Total estimated dollar value and performance/delivery period.

Estimated dollar value: \$118,848
Award date to September 30, 2009

- d. Recovery Act funding.** This action is funded by the Recovery Act, which specifies, in part, "To the maximum extent possible, contracts funded under this Act shall be awarded as fixed-price contracts through the use of competitive procedures." Since this action will not be awarded through competitive procedures, since a summary of this action must be posted to the special section of Recovery.gov, and since this JFOC must be posted to FedBizOpps; reviewers should scrutinize this justification for adequacy and completeness.

4. Identification of the statutory authority permitting other than full and open competition.

- ☒ This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 253(c)(1) as set forth in Federal Acquisition Regulation (FAR) 6.302- 1.
- ☐ This acquisition is conducted under the authority of section 4202 of the Clinger-Cohen Act of 1996.
- ☐ This acquisition is conducted under the authority of the Services Acquisition Reform Act of 2003 (41 U.S.C. 428a).

5. Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.

a. Name and address of the proposed contractor(s).

Parallabs, Inc.
67 Millbrook Street , Suite 522
Worcester, MA 01606-2835

b. Nature of the acquisition and proposed unique qualifications of the contractor(s).

The Chemagic Magnetic Separation Module (MSM) is an automated DNA extraction instrument. It achieves walk-away, high throughput DNA and RNA purification from a variety of specimens such as blood, tissue and cells. Its 12x18 sample format is highly adaptable to downstream laboratory procedures, further increasing the efficiency of testing.

Parallabs, Inc. is the only United States distributor of the MSM 1. This is the only commercially available instrument that has a complete solution for the preparation of nucleic acids from blood, serum/plasma, swabs, saliva, faeces, etc.

The MSM 1 is the only instrument that has exchangeable rod heads that allow for processing of 96 or 48 well plates using the 96 head, or 24 well plates using the 24 rod head. In addition, a 12 Rod head allows for large single tubes when working volumes up to 50 ml. Magnetic separation avoids the use of filters and vacuums that may clog. The rods are covered with disposable shields preventing sample-to-sample contamination.

The software allows the user to adjust all parameters of the DNA purification process (i.e., buffer volumes, incubation times, etc.).

Sample in-and-output formats are flexible and permit the downstream integration of other proven laboratory hardware and sample storage systems. Additional key features include:

- One instrument for sample volumes of 10ul to 10 ml.
- QA software.
- No need to desalt, samples are in buffer.
- No need to dry, alcohol is removed in process.
- Sample is ready for use immediately after run is finished and amount of final sample can be predetermined.
- Can be combined with standard liquid handling.
- Barcode reading.
- LIMS compatible log files.

The MSM 1 can be equipped with an automatic dispenser, which prefills fast and accurately the tubes/plates during run. The dispenser is fully integrated with MSM 1 software, minimizes manual input as well as waste of buffer and complements the system to complete walk-away automation.

- 6. Description of the efforts made to ensure that offers are solicited from as many potential sources as practicable. Indicate whether a FedBizOpps notice was or will be publicized as required by FAR Subpart 5.2 and, if not, which exception under FAR 5.202 applies.**

Other commercially available DNA extractors were reviewed to determine if other equipment might be available to satisfy the laboratory's requirements for full walk-away automation, 96-sample throughput, high quality/purity of DNA applicable to PCR, sequencing and hybridization assays, versatility in sample volume, specimen type, extraction parameter setting adjustable by user, reliability, and cost of extraction reagents.

Specific equipment reviewed: (1) the BioRobot Universal (Qiagen) is based on silica membranes for binding and purifying DNA. From the experience in our current non-automated system this technology poses problems with certain sample types and specimen collection media, resulting in clogging and incomplete DNA purification. (2) The "Bullet" (Norgen) and the QiaSynphony are two automated systems that are based on magnetic bead purification technology. Neither of these is an open system and applications are therefore restricted to certain conditions and specimen types. (3) The AutoGenPrep 965 (AutoGen) uses solution phase organic separation for DNA purification at a low per-sample cost. An evaluation by the National Genetics Reference Laboratory (Wessex, U.K.) documents inferior quality and purity of nucleic acids.

A notice of the proposed contract action was publicized in FedBizOpps as required by FAR Subpart 5.2. This notice was reviewed by the Office of Enterprise Communications to ensure that the requirement was stated plainly and clearly. No response was received from any vendor inquiring about the requirement during the synopsis period of 15 days which ended on 1 June 2009.

The Chemagic MSM1 system is the only complete, versatile solution. See paragraph 5b for specifics.

- 7. Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.**

Fair and reasonable pricing will be verified via price analysis of commercially available catalog pricing.

- 8. Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.**

The HPV laboratory conducted an internet search and consulted the literature including a review by the National Genetics Reference Laboratory, Wessex, U.K. to identify instruments that met criteria stated in paragraph 6 above. The Chemagic system, based on magnetic beads, will avoid the potential for clogging associated with membrane-based systems, and is the most complete, versatile system available.

- 9. Any other facts supporting the use of other than full and open competition.**

No.

10. Listing of sources, if any, that expressed, in writing, an interest in the acquisition.



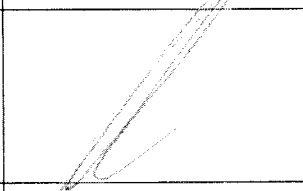
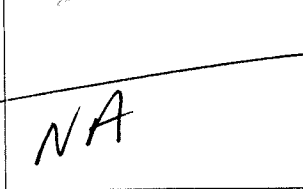
No other sources have expressed an interest, in writing, in the proposed acquisition. As indicated in paragraph six (6) above, no interested parties responded to the Government during the synopsis of the requirement. However, any and all responses received at any time during the process will be thoroughly reviewed to determine if sources previously unknown exist and might be considered for competition.

11. Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.

There are no plans to acquire this equipment in the future.


12. Program office certification.

This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Official	Name & Title	Signature	Date
Project Officer	Joann House		5/13/2009
	Elizabeth Unger		5/13/2009
Project Officer's Immediate Supervisor	William C. Reeves		5/13/2009
Head of the Sponsoring Program Office	Jane Seward		

13. Contracting Officer certification.

This is to certify that the justification for the proposed acquisition has been reviewed and that to the best of my knowledge and belief the information and/or data provided to support the rationale and recommendation for approval is accurate and complete.

Official	Name & Title	Signature	Date
Contracting Officer	CHARLENE R. ALLISON		8/7/09

14. Chief of the Contracting Office and Head of the Contracting Activity signature(s).

Official	Name & Title	Signature	Date
Chief of the Contracting Office	NA		
Head of the Contracting Activity			

15. Competition Advocate signature.

Official	Name & Title	Signature	Date
Competition Advocate	NA		

16. HHS Senior Procurement Executive signature.

Official	Name & Title	Signature	Date
HHS Senior Procurement Executive	NA		